

REMARKS

Upon entry of the amendments herein, claims 1-6, 8-10 and 12-33 remain pending in the application. Claims 1, 12, 15, 25 and 33 have been amended herein.

Claim 12 has been objected to for lack of antecedent basis for reciting the phrase "the closed circumferential element." The claim has been amended as suggested by the Examiner.

In light of Applicants' last response, all of the previous prior art rejections have been withdrawn by the Examiner. However, the Examiner has now leveled three new prior art rejections. Two of these rejections are completely based on newly cited references and the third is based on a combination of newly cited references and one reference previously cited.

Claims 1-6, 8, 9, 14-21, 24-29, 32 and 33 stand newly rejected under 35 U.S.C. §102(b) as being anticipated by newly cited U.S. Patent No. 5,925,061 to Ogi et al. Applicants disagree with this assessment.

In the first place, the Examiner has copied Figure 8 from the Ogi reference into the Office Action and asserted that the figure shows "a first helix comprising a plurality of nonsinusoidal zigzags...." [Emphasis added.] During the February 9, 2005 interview with the Examiner and her Supervisor, various terms, including "sinusoidal" and "zigzag" were discussed and it was agreed among all interview participants that the latter term

is considered broader and would encompass the former. This outcome of the interview was set forth in Applicants' previous response in connection with the amendments made to the claims in that response to specify that the undulations of the helical elements are nonsinusoidal.

It is not understood by Applicants how the Examiner could label the undulations shown in Ogi Figure 8 as nonsinusoidal. Said undulations clearly fit the typical definition of a sinusoidal pattern and are in contrast to the zigzags of the instantly claimed stents which are clearly nonsinusoidal in nature. The Ogi disclosure bears out this assessment of the nature of the Ogi undulations. It must be noted, for example, that Ogi, et al., in describing Fig. 1 in column 4, lines 23-26, disclose that the stent "comprises a continuous mesh pattern of sinusoidal [emphasis added] or undulating member 15..." The corresponding members depicted in Ogi Figure 8, cited by the Examiner, are no less sinusoidal than member 15 of Figure 1. Thus, on this basis alone, it cannot be said that the Ogi reference teaches each and every element recited in the instant claims. Ogi is thus ineffective as an anticipatory reference.

Furthermore, in the copy of Ogi Figure 8 inserted into the Office Action, the Examiner has drawn in arrows showing an alleged "First helix" and an alleged "Second helix." However, the "First helix" is the only helix shown in Ogi Figure 8. The

Examiner's attention is directed to the Ogi passage running from column 2, line 63 through column 3, line 14. In the first place, Ogi, et al. themselves describe their stent as one having a single helical structure. Secondly, the "bridges" (i.e., the Ogi connection elements) that connect adjacent windings of the single helical structure are disclosed merely to be "helically arranged."

A helical arrangement of connecting elements does not, as particularly exemplified by the Ogi stent, necessarily constitute or lead to an actual helical structure, such as that found in the instant stents. Applicants note further that the Examiner could just as easily have drawn in an arrow pointing from the lower left side to the upper right side of the figure to show the progression of helically arranged connection elements allegedly creating a "Second helix." Either way, the arrow does not trace a true helix. The Examiner's assessment of what Figure 8 shows is in error.

Furthermore, as the Examiner acknowledges (and as can be seen in, for example, Ogi Figure 8), the links of the Ogi stent connect from peak to peak of adjacent turns of the helix. It is clear, however, that the links in the instant stents connect peaks to valleys. In anticipation of the possibility that the Examiner would assert that this distinguishing feature of the instant stents is not recited in the claims, Applicants have

amended the instant claims to make clear the nature of the links made by the connection elements of the instant stents.

Still further, it is clear from Ogi Figure 8 that the connecting elements are strictly parallel to the longitudinal axis of the stent. This is further confirmed by Ogi's description in column 9, lines 24-37 of Figure 8 and the nature of the connecting elements. As made clear by Ogi, this parallel orientation of the connecting bridges is desirable because their role is in longitudinally strengthening the stent. On the other hand, it is clear from the instant figures that the connection elements do not, and cannot, run parallel to the longitudinal axis of the stent. Again, Applicants have amended the claims to literally add this distinction.

In order for a reference to be effective as an anticipatory reference, it must disclose each and every element of the claimed invention. Clearly, the Ogi stents lack several features of the instant stents and thus fall well short of meeting the criteria for constituting a bar to patentability.

Claims 10, 12, 22, and 30 stand newly rejected under 35 U.S.C. §103(a) as being obvious over the same Ogi patent in view of newly cited U.S. Patent No. 6,352,552 to Levinson et al. Again, Applicants disagree with this assessment.

The claims in this rejection recite a closed circumferential element, and the Examiner has invoked Levinson as disclosing

this component, which is acknowledged to be missing from the Ogi disclosure. However, as the Examiner also acknowledges, the pattern of the Levinson stent "includes a continuous sinusoidal helix...." [Emphasis added.] As clearly set forth above, the primary Ogi reference is deficient in, among other things, teaching a nonsinusoidal helical element. Thus, whether or not Levinson discloses closed circumferential elements, by the Examiner's own admission this secondary reference does not teach at least one feature of the present stents that is clearly missing from the primary reference. Furthermore, clearly, the Levinson reference does not disclose other features of the instant stents on which, as shown above, the primary reference is silent. Thus, the secondary reference cannot be said to make up for the gaps in the teaching of the primary reference, and this combination of references is ineffective in rendering obvious the instantly claimed stents.

Claims 13, 23 and 31 stand newly rejected under 35 U.S.C. §103(a) as being obvious over the same Ogi and Levinson Patents and further in view of U.S. Patent No. 6,315,794 to Richter, previously made of record. Once again, Applicants disagree with this assessment.

The claims in this rejection recite that the closed circumferential element is radiopaque and the Examiner invokes the Richter reference as disclosing this feature, which feature

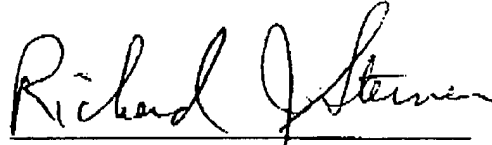
is acknowledged to be missing from the disclosure of the Ogi and Levinson references. Again, however, whether or not Richter teaches this feature, it is silent with respect to several other features of the instant stents which are clearly missing from both Ogi and Levinson. Again, for example, the undulations of the Richter stent are clearly sinusoidal in nature and thus the Richter reference cannot be seen as one which makes up for the deficiencies of the primary and secondary references.

The amendment herein of claim 12 overcomes the Examiner's objection. As shown above, the Ogi reference is ineffective as an anticipatory reference. This fact, along with the amendments made herein to further clarify some of the features of the instant stents that make them distinct from those of the cited prior art, makes it clear that neither Ogi by itself, nor Ogi in combination with one or both of the other cited references, is effective as a bar to patentability of the presently claimed subject matter. Reconsideration and allowance of the application with pending claims 1-6, 8-10 and 12-33 are respectfully requested. Should any other matters require attention prior to allowance of the application, it is requested that the Examiner contact the undersigned.

The Commissioner is hereby authorized to charge any additional fees which may be due for any reason to Deposit Account No. 23-1703.

Date: December 21, 2005

Respectfully submitted,

A handwritten signature in cursive script, reading "Richard J. Sterner", written over a horizontal line.

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